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DATA EVALUATION REPORT V

STUDY TYPE: Primary Eye Irritation - rabbit

TOX. CHEM. NO: 316

ACCESSION NUMBER: not given

MRID NO: 128854

TEST MATERIAL: 2,4-DB

SYNONYMS: 4-(2,4-dichlorophenoxy)butyric acid

STUDY NUMBER(S): Project Report 45-188

SPONSOR: Union Carbide Agricultural Products Co.

TESTING FACILITY: Bushy Run Research Center

TITLE OF REPORT: Technical 2,4-DB Acid: Acute Toxicity
and Irritancy Studies

AUTHOR(S): Myers, R., Coleman, J., Bellich, N. et al.

REPORT ISSUED: 11/24/82

Classification: Core minimum

Special Review Criteria (40 CFR 154.7)

Toxicity category: III

CONCLUSIONS:

1. The study is acceptable as core minimum data.
2. Technical 2,4-DB is in toxicity category III in terms of its eye irritation potential. Although eye irritation (including corneal involvement) was noted in this study in a number of unwashed rabbit eyes, there was complete clearing in each case by day 7.

A. MATERIALS:

1. Test compound: 2,4-DB Technical, Description: a fine white powder. Identification number: RPM 2827AE. Purity (reported by the sponsor): 98%. Material used was received July 15, 1982.
2. Test animals, Species: rabbit; Strain: New Zealand White, about 12-18 weeks of age (weighing between 2.0 and 3.0 kg). Rabbits were obtained from Three Springs Kennels (Jackson Center, PA), and were acclimatized for at least 5 days before they were used.

B. STUDY DESIGN:

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1. Application

0.1 g of the test material was applied to one eye of each of 9 rabbits. Three eyes were rinsed with lukewarm water at 20 to 50 seconds after instillation. The other 6 eyes remained unwashed.

2. A signed Quality Unit Study Inspection Summary is provided on p. 25 of the report.

C. METHODS AND RESULTS:Observations

Readings were made at 1, 2, 3, 4 and 7 days, with fluorescein staining.

Results:

5/6 unwashed eyes showed some irritation (with corneal involvement) at 24 hrs. None of the washed eyes showed any irritation. All eyes showed no irritation on day 4 or subsequently.

D. DISCUSSION:

The study is acceptable as core minimum data. Technical 2,4-DB is in toxicity category III in terms of its eye irritation potential (irritation clearing by day 7).